K042060 1 of 2

OCT 6 - 2004

510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

Submitter's Name:	Millimed A/S
Submitter's Address:	Langebjerg 2 DK-4000 Roskilde Denmark
Telephone:	+45 4676 1420
Fax:	+45 4676 1970
Contact Person:	Jannie Funch, Quality Manager
Date Prepared:	July 30, 2004
Device Trade Name:	EasyPass™ US Y-connector Hemostatic Valve
Device Common Name:	Hemostasis Device
Device Classification Name:	Cardiovascular Surgical Devices
Device Classification:	Class II

Summary of Substantial Equivalence:

The EasyPass Y-connector Hemostatic Valve is substantially equivalent to Guidant Corporation's Copilot Bleedback Control Valve (K991102)

Device Description:

The EasyPass™ US Y-connector Hemostatic Valve consists of a y-connector body with a rotating luer lock, a sidearm and a hemostasis valve. To open the hemostasis valve, a valve opener cap with a center passage tube is pushed distally. The hemostasis valve is closed by pulling the valve opener cap proximally. The passage tube on the valve opener provides a completely opened and smooth lumen for the insertion of interventional devices.

Intended Use:

The EasyPass™ US Y-connector Hemostatic Valve is intended to maintain hemostasis during the introduction, use and withdrawal of diagnostic and interventional devices that have an outer diameter of 7 French or smaller.

The guide wire insertion tool facilitates introduction of the guide wire through the hemostasis valve and into the guiding catheter.

The torquer, inserted over the proximal end of the guide wire, provides a handle for easier manipulation of the guide wire.

Technological Characteristics:

Comparisons of the new and predicate device show that technological characteristics such as device design and principle of operation are substantially equivalent to the currently marketed predicate device.

Performance Data:

The results of the performance testing demonstrated the safety and effectiveness of the EasyPass™ US Y-connector Hemostatic Valve.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 - 2004

Millimed A/S
c/o Ms. Jannie Funch
Quality Manager
Langebjerg 2
DK-4000 Roskilde
Denmark

Re: K042060
EasyPass™ US Y-connector hemostatic Valve
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, or Fitting
Regulatory Class: Class II (two)
Product Code: DTL
Dated: July 30, 2004
Received: July 30, 2004

Dear Ms. Funch:

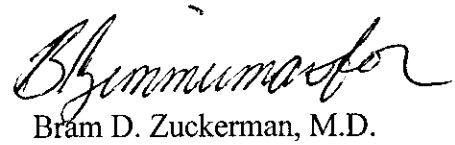
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K042060

Indications for Use Statement

510(k) Number (if known)

Device Name EasyPass™ US Y-connector Hemostatic Valve

Indications for Use

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The torquer, when inserted over the proximal end of the guide wire, provides a handle for easier manipulation of the guide wire.

Prescription Use ____X____ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042060